**MHCC Primary PCI Waiver Application**

Docket Number

**Please type or print legibly. Do not leave any items blank. Enter "0" or "N/A" in items that do not apply to the applicant. Incomplete applications will be returned without further action.**

Application Due Date _____ Date Submitted _____

Type of Application Initial ___ Resubmission ___ Renewal ___

*The applicant must notify MHCC in writing immediately if the information in this application changes materially.*

| For MHCC Use Only | |
|---|---|
| Application Received | |
| Application Revised | |

## SECTION A - APPLICANT IDENTIFICATION

Name of Applicant _____

Street Address _____

Mailing Address (if different) _____

City _____ County _____ State _____ ZIP Code _____

Applicant's Medicare Provider Number(s) _____ _____

Is the applicant a Medicare Provider in good standing? Yes ___ No ___ If "No," **attach an explanation**.

*Location of Primary PCI Program (if different from above):*

Street Address _____

City _____ County _____ State _____ ZIP Code _____

*Person to be contacted on matters involving the application:*

Name _____

Title _____

Street Address _____

City _____ County _____ State _____ ZIP Code _____

Telephone Number _____

Fax Number _____

Email Address _____

## SECTION B - APPLICANT STATUS

(a) Is the applicant currently providing primary PCI? Yes ___ No ___

(b) Has the applicant participated in the C-PORT primary PCI registry? Yes ___ No ___

If "Yes," **submit a letter from the Director, Atlantic C-PORT**, stating that all data are completed. *The applicant must submit the letter to MHCC no later than 210 calendar days after the last PCI patient entered the C-PORT registry. MHCC will grant a provisional waiver during this period, provided the applicant has met all other requirements. After this time, a full waiver will be either approved or denied.*

| For MHCC Use Only | |
|---|---|
| C-PORT Letter Submitted | |

## SECTION C1 - ESTABLISHED PROGRAM

(a) Does the institution provide primary PCI as routine, treatment of choice for all appropriate AMI patients 24 hours per day, seven days per week? Yes ___ No ___

(b) Starting with the most recent 12-month period, list the number of primary PCI procedures performed annually during the last two years.

| | From (Mo/Day/Yr) | To (Mo/Day/Yr) | Number of Procedures |
|---|---|---|---|
| Year 1 | | | |
| Year 2 | | | |

## SECTION C2 - DEVELOPMENT PROGRAM

(a) Starting with the most recent 12-month period, list the number of acute ST-segment elevation MIs cared for annually during the last two years.

| | From (Mo/Day/Yr) | To (Mo/Day/Yr) | Number of STEMIs |
|---|---|---|---|
| Year 1 | | | |
| Year 2 | | | |

(b) **Attach a detailed description** of how the hospital proposes to undertake and complete a development program, which may include collaboration with an established PCI program. The development program should contain the following major components, as specified in COMAR 10.24.17:

(i) Use of American College of Cardiology/American Heart Association Guidelines to guide care;
(ii) Additional training of nursing and technical staff in both the catheterization laboratory and in pre- and post-procedure care units;
(iii) Logistical issues, including, at a minimum, hours of operation, who obtains consent, mechanisms to gather staff, mechanisms to assure availability of staff and catheterization laboratory, plans for recurrent ischemia or infarction, plans to determine the responsible physician during and after primary PCI, plans for failed PCI, and fall-back plans for primary PCI system failure; and
(iv) Quality and error management.

*Organization or institution conducting the formal development program:*
Name _____

(c) **Attach a detailed description** of how the hospital proposes to undertake and complete data collection and reporting requirements.

## SECTION D - PHYSICIAN RESOURCES

1. Identify the physician director of interventional cardiology services responsible for defining and implementing credentialing criteria for the catheterization laboratory and for overall primary PCI program management.

Name _____

Title _____

Street Address _____

City _____ County _____ State _____ ZIP Code _____

Telephone Number _____

Fax Number _____

Email Address _____

2. **Attach a list** of the cardiologists who have privileges to perform primary PCI, including the name of the cardiologist; an indication of those physicians newly out of fellowship (less than three years); an indication of those physicians who participate in an on-call schedule; and the number of PCI cases each cardiologist performed at the applicant institution and other institutions per year for the past 24 months. **Submit an updated annual list for each year of the waiver.**

## SECTION E - REQUIRED ATTACHMENTS

1. Written commitment by hospital administration signed by the hospital president to support the primary PCI program.

2. Formal, written agreement with a tertiary institution that provides for unconditional transfer of patients for any required additional care, including emergent or elective cardiac surgery or PCI, and timely transmission of required follow-up data on transferred patients.

3. Formal, written agreement with an advanced cardiac life support emergency medical services provider that guarantees arrival of the air or ground ambulance within 30 minutes of a request for patient transport.

4. Documentation of required attendance at formal, regularly scheduled interventional case reviews by a critical mass of interventionalists and other physicians, nurses, and technicians who care for primary PCI patients.

5. Documentation of a multiple care area group that includes, at a minimum, the physician and nursing leadership of each care area and meets monthly to review any and all issues related to the primary PCI system, identify problem areas, and develop solutions.

6. Copies of other documents required and identified in sections A, B, C, and D.

## SECTION F - APPLICANT AFFIDAVIT

*I solemnly affirm under penalties of perjury that the contents of this application, including its attachments, are true and correct to the best of my knowledge, information, and belief. I understand that MHCC may issue a waiver if the applicant has demonstrated or can demonstrate the ability to comply with all requirements for primary PCI programs without on-site cardiac surgery. As a condition of issuance of a waiver to perform primary PCI procedures without on-site cardiac surgical backup, the applicant agrees to collect and report complete and accurate data as specified by MHCC. I further affirm that this waiver application has been duly authorized by the governing body of the applicant, and the applicant will comply with the terms and conditions of the waiver and applicable State requirements. I understand that deliberate falsification of information in this application may constitute grounds for its rejection. I further understand that a primary PCI waiver may be renewed by the Commission upon request by the hospital provided that the hospital has met and will continue to meet all requirements for primary PCI programs without on-site cardiac surgery. The applicant acknowledges that the Commission may revoke the waiver at any time for failure to comply with the requirements, terms, or conditions of the waiver or applicable State requirements.*

Signature of Owner or Board-designated Official _____

Date _____

| For MHCC Use Only | |
|---|---|
| Application Returned | |
| Application Docketed | |
| Provisional Waiver Granted | |
| Provisional Waiver Denied | |
| Waiver Approved | |
| Waiver Denied | |
| Waiver Revoked | |
| Applicant Notified | |
| Applicant Notified | |
| Applicant Notified | |

## INFORMATION REGARDING APPLICATION FOR PRIMARY PCI WAIVER

The Maryland Health Care Commission has sole authority to review and approve applications for waiver of the requirement for on-site cardiac surgical backup under COMAR 10.24.17.05D(1), and to revoke a waiver granted under the regulation.

The Commission will review applications according to the schedule published by the Commission in the *Maryland Register*. The Commission will review each application for completeness as received. The Commission will docket all applications that it determines are complete and publish a notice of the docketing in the *Maryland Register*.

The applicant may make changes to its application on or before the published deadline for submitting applications. If any events should occur that materially change the facts, statements, or representations made in the application, the applicant shall notify the Commission in writing immediately.

The applicant shall cooperate with the Commission or any of its authorized representatives in the conduct of audits. This cooperation includes access without unreasonable restrictions to records and personnel of the applicant for the purpose of obtaining or validating relevant information.

The Commission will notify the applicant of its decision to grant, deny, or revoke a waiver in writing.

The Commission will issue a primary PCI waiver for a two-year period, provided that the hospital meets and continues to meet all requirements for primary PCI programs without on-site cardiac surgery. The hospital must submit an application for renewal before its current waiver is scheduled to expire.

The applicant must submit an original application with actual ink signature and three copies of the completed application to:

Rex W. Cowdry, M.D.
Executive Director
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

If you have any questions regarding the form, please contact:

Pamela W. Barclay
Deputy Director, Health Resources
410-764-3232